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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,784	06/19/2001	Sara Petersen Bjorn	0459-0615P	8714
2292	7590 06/17/2003			
BIRCH STE	WART KOLASCH &	EXAMI	EXAMINER	
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FALLS CHUI	RCH, VA 22040-0747			,
			ART UNIT	PAPER NUMBER
			1653	1
			DATE MAILED: 06/17/2003	(10

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
	_	09/887,784	BJORN ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Hope A. Robinson	1653			
	The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
	Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on <u>02 J</u>					
2a)	,	is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-19 is/are pending in the application.						
4a) Of the above claim(s) 10 and 13-19 is/are withdrawn from consideration.						
5) Claim(s) 9,11 and 12 is/are allowed.						
6) Claim(s) <u>1-8</u> is/are rejected.						
7)	Claim(s) is/are objected to.					
8   Claim(s) are subject to restriction and/or election requirement.   Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)☐ Some * c)☐ None of:						
	1. Certified copies of the priority document	s have been received.				
	<ol><li>Certified copies of the priority document</li></ol>	s have been received in Applicati	on No			
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).      See the attached detailed Office action for a list of the certified copies not received.						
14) 🖾 Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) ☑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s)						
J.S. Patent and Tr	ademark Office					

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### **DETAILED ACTION**

### Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-12 (SEQ ID NO:) are drawn to a fluorescent protein, classified in class 530, subclass 350.
  - II. Claims 13-18 (SEQ ID NO:) are drawn to a nucleotide sequence, classified in class 536, subclass 23.1.
  - III. Claim 19 is drawn to a method for measuring protein kinase activity, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Inventions I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes a protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for process other than the production of the protein, such as nucleic acid hybridization assay.

Invention I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

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for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA and protein can be used in a materially different process for example, the protein can be used to make antibodies.

Invention II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA and protein can be used in a materially different process for example, the DNA can be used in a hybridization assay.

Several of the inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved.

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The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

2. During a telephone conversation with Mr. Craig McGrabbie on June 2, 2003, a provisional election was made with traverse to prosecute the Invention of Group I, Claims 1-12 (SEQ ID NO:4). Affirmation of this election must be made by applicant in responding to this Office action. Claims 13-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142 (b), as being drawn to a non-elected invention.

### Claim Disposition

Claims 1-19 are pending. Claims 1-9 and 11-12 are under examination. Claim 10
and 13-19 are withdrawn from consideration as directed to a non-elected
invention. Note that based on the election of SEQ ID NO: 4, claim 10 is
withdrawn.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because the claim recites "65-57" for a range in amino acid position. The claim also lacks antecedent basis as no support was found in the instant specification for that range. In addition, a specific sequence must be provided that corresponds to the recited range, and please note that dependent upon the elected sequence the actual residue positions may differ.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

6. Claims 1-8 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Thastrup et al. (WO 97/11094 March 27, 1997) in view of Tsien et al. (US Patent No. 6,124,128, August 30, 1996.

Thastrup et al. teach a fluorescent protein derived from GFP (Aequorea green fluorescent protein) or any functional analogue thereof wherein the amino acid in position 1 preceding the chromophore has been mutated to provide an increase of fluorescence intensity. Thastrup et al. teach that the proteins exhibit high fluorescence in cells expressing them when said cells are incubated at a temperature of 30 degrees or above. Thastrup et al. also teach that the chromophore is in position 65-67 and the substitution of F at position 64 for an aliphatic amino acid (see pages 1-4, claims 1-4 of the instant application). Thastrup et al. teach that the preferred mutation is F64L (claims 5-6), however, deletions, substitutions, insertions or posttranslational modifications immediately preceding the chromophore are also included in the invention, however is silent on the E222G mutation recited in claim 1 of the instant specification. However, Tsien et al. teach the E222G mutation (see column 3, line 56, claim 8). Tsien et al. teach "a functional analogue" of GFP as it is disclosed that there is substantial homology between the protein of the invention and Aequorea GFP (column

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3, line 10). Tsien et al. teach the mutation E222X, wherein X is N or Q (column 4, line 12, claim 7).

Therefore, it would have obvious for one of ordinary skill in the art at the time the invention was made to modify the teachings of Thastrup et al. (GFP mutation F64L) by adding in the teachings of Tsien et al. (GFP E222G) to arrive at the claimed invention as a whole. One of ordinary skill in the art would be motivated to combine the teachings of the references because Thastrup et al., disclose that other mutations are possible preceding the chromophore provided that they result in improved fluorescence properties of the various fluorescent proteins (page 4, lines 10-15). Thus, the claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

#### Conclusion

7. Claims 9, 11 and 12 are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

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Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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